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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,185	07/18/2001	C. Frank Bennett	RTS-0258	1505

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Jane Massey Licata  
Licata & Tyrrell, P.C.  
66 East Main Street  
Marlton, NJ 08053

EXAMINER
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ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/910,185	<b>Applicant(s)</b> BENNETT ET AL	
	<b>Examiner</b> Jane Zara	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office action is in response to the communication filed 9-25-03.

Claims 1, 2, 4-10, 12-15 are pending in the instant application.

#### ***Response to Arguments and Amendments***

##### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

##### **Maintained Rejections**

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalff-Suske et al for the reasons of record set forth in the Office action mailed 6-27-03.

Applicant's arguments filed 9-25-03 have been fully considered but they are not persuasive. Applicants argue that Kalff-Suske et al do not anticipate the claimed invention because the antisense oligonucleotides disclosed by Kalff-Suske et al were used to perform single strand conformation analysis and consequently to identify variants of the target sequence. Contrary to Applicants' assertions, the antisense oligonucleotides utilized by Kalff-Suske et al, although used successfully to perform a different technique than in vitro target gene inhibition of human glioma associated oncogene-3, comprise antisense oligonucleotides that specifically hybridize with a nucleic acid molecule encoding human glioma associated oncogene 3, which antisense oligonucleotides inhibit the expression of the target gene in vitro. The use of an antisense oligonucleotide claimed in the instant invention for another technique does

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not change that compound's properties. Therefore, the 102 rejection is maintained as applicable to the antisense compound claims 1 and 2.

Claims 1, 2, 4-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalff-Suske et al and Ruppert et al, the combination in view of Milner et al and Baracchini et al.

Applicant's arguments filed 9-25-03 have been fully considered but they are not persuasive. Applicants argue that the instant 103 rejection is improper because the primary references of Kalff-Suske et al and Ruppert et al do not teach the limitations of the claimed invention, and combined with the references of Milner and Baracchini, do not therefore qualify as a prima facie case of obviousness. Contrary to Applicants assertions, the antisense utilized by Kalff-Suske anticipate the antisense oligonucleotide compound claims 1 and 2, which antisense oligonucleotides specifically hybridize with the human glioma associated oncogene-3 target gene and inhibit the target gene's expression in vitro, as discussed above. This reference does not anticipate all of the limitations of claims 4-10 and 12-15, and so is cited properly under an obviousness, not an anticipated, rejection because the antisense oligonucleotides that specifically hybridize and inhibit the expression of human glioma associated oncogene-3 in vitro lend themselves to the modifications described by Baracchini and to the method of in vitro target gene inhibition described by Milner and generally applicable to in vitro inhibition of a target gene of known nucleic acid sequence.

Ruppert et al is relied upon in the instant 103 rejection because it discloses the nucleotide sequence of the human glioma associated oncogene-3, and, together with

the routine method described by Milner (i.e. for antisense design and assessment of in vitro target gene inhibition using antisense, which target gene nucleotide sequence has been previously disclosed), render the claimed invention obvious. Ruppert et al is additionally relied upon as providing motivation to inhibit the expression of human glioma associated oncogene-3 because Ruppert teaches that increased expression of the target gene occurs in various tumors. Human glioma associated oncogene-3 is thought to participate in the neoplastic process, likely by participating in transcriptional control processes. Ruppert does not anticipate all of the limitations of claims 1, 2, 4-10 and 12-15, and so is cited properly under an obviousness, not an anticipated, rejection because, in combination with the supporting references of Milner and Baracchini, render the instantly claimed invention obvious. Milner, as described above, teaches the general method of designing and assessing antisense for their ability to target and inhibit the expression of a target gene of known nucleic acid sequence in vitro and Baracchini teaches the modifications claimed in the instant application, which modifications are incorporated into antisense molecules generally and are not sequence specific modifications. Therefore, the instant 103 rejection is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

December 9, 2003

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**